

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

In re:	:	MDL No. 2419
	:	Docket No. 1:13-md-2419 (FDS)
NEW ENGLAND COMPOUNDING	:	
PHARMACY, INC. PRODUCTS	:	
LIABILITY LITIGATION	:	Judge F. Dennis Saylor, IV
	:	
THIS DOCUMENT RELATES TO	:	
	:	
ALL ACTIONS	:	
_____	:	

**PAIN MEDICINE SPECIALISTS, P.A.'S OBJECTIONS TO
PLAINTIFFS STEERING COMMITTEE'S SUBPOENA TO TESTIFY AT A
DEPOSITION IN A CIVIL ACTION AND MOTION TO QUASH**

Pain Medicine Specialists, P.A. ("Pain Medicine Specialists"), by its undersigned counsel, files its objections to the Subpoena for a deposition and the production of documents ("the Subpoena"). This Subpoena was issued on behalf the Plaintiffs' Steering Committee ("PSC") in this case ("MDL"). The Subpoena commands a deposition along with production of various documents. Pain Medicine Specialists respectfully files these objections and requests that the Court quash or modify the Subpoena or, in the alternative, issue a protective order under Rule 26(c).¹

PRELIMINARY STATEMENT

Pain Medicine Specialists is a medical practice located in Baltimore, Maryland. Pain Medicine Specialists is a non-party to the MDL action. The PSC sent via United States Postal mail a Subpoena to Pain Medicine Specialists. Shortly thereafter, based on

¹ In filing this objection, Pain Medicine Specialists make only a limited appearance for the purpose of filing this objection and does not concede or admit to the personal jurisdiction of this Court or the State of Massachusetts nor does it concede that Due Process has been complied with in the nature of any previous orders or proceedings in this Court which have not been properly served on Pain Medicine Specialists and given it appropriate notice and time to object. The PSC has not been serving copies of all materials filed in this Court on all interested parties who are not parties to this litigation such as Pain Medicine Specialists.

the objections of other subpoenaed witnesses, the PSC sent Pain Medicine Specialist an amended document request. Rather than contest the adequacy of service, pursuant to agreement of counsel, a response to the Subpoena was due on or before August 16.

With very few exceptions, the Subpoena's requests are not remotely relevant to the claims at issue in the MDL, they are not calculated to lead to the discovery of admissible evidence in the MDL and they do not comply with the privacy rights of patients consistent with Maryland law. For example, the Subpoena seeks information about Pain Medicine Specialists' organizational structure and insurance coverage; information that has no bearing on the liability of NECC or any other defendants in the MDL. Instead, the Subpoena is little more than an improper fishing expedition to obtain discovery from Pain Medicine Specialists for the purpose of either preparing for claims against Pain Medicine Specialists and/or reaching additional potential claimants. Plaintiffs should not be permitted to use the power of this Court to impose these burdensome and impermissible requests on Pain Medicine Specialists, a non-party to this action which does not even have patients who are potential victims who have claims against NECC.

Accordingly, for these reasons and the reasons set forth below, Pain Medicine Specialists objects to the Subpoena in its entirety.

GENERAL OBJECTIONS

1. In objecting to this Subpoena, Pain Medicine Specialists does not concede the existence, relevance, materiality, or admissibility of the Subpoena, the information, the documents or the testimony to which the Subpoena refers or relates or that this Court has personal jurisdiction over it.
2. Pain Medicine Specialists objects to PSC's Requests under Fed. R. Civ. P. 26(b)(2)(C)(i) to the extent that the information sought from a third party to the

litigation is unreasonably cumulative or duplicative of information already provided to the PSC by New England Compounding Pharmacy, Inc.

3. Pain Medicine Specialists objects to PSC's Requests under Fed. R. Civ. P. 26(b)(2)(C)(i) to the extent that the information sought from a third party to the litigation can be obtained from some other source such as public records and/or New England Compounding Pharmacy, Inc. that is more convenient, less burdensome or less expensive.
4. Pain Medicine Specialists objects to PSC's Requests to the extent they seek to impose on Pain Medicine Specialists any obligations or responsibilities other than those required by the Federal Rules of Civil Procedure or the applicable Local Civil Rules of the United States District Court for the District of Maryland.
5. Pain Medicine Specialists objects to PSC's Requests to the extent they seek production of documents protected from discovery by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Nothing contained in these objections is intended to be, or in any way constitutes, a waiver of any such applicable privilege or immunity.
6. An objection asserting that a Request seeks privileged information or documents should not be construed as a representation that such information or documents exist or existed. Such objections indicate only that the Requests are of such a scope as to embrace subject matter protected by the attorney-client privilege, the work-product doctrine or other applicable privilege or immunity.
7. Pain Medicine Specialists objects to PSC's Requests to the extent they seek production of documents and things subject to confidentiality rights of third

parties not affiliated with Pain Medicine Specialists.

8. Pain Medicine Specialists objects to PSC's Requests to the extent they seek to require Pain Medicine Specialists to produce documents requiring more than a reasonable search to identify.
9. Pain Medicine Specialists objects to PSC's Requests to the extent they seek production of duplicative materials.
10. Pain Medicine Specialists objects to PSC's Requests as vague, ambiguous, and unduly burdensome to the extent they seek the production of "any and all documents."
11. Pain Medicine Specialists objects to PSC's Requests to the extent they seek the production of documents that contain information that is not relevant to a claim or defense of the parties or is not reasonably calculated to lead to the discovery of admissible evidence. Pain Medicine Specialists reserves the right to redact such information before producing documents to PSC.
12. Pain Medicine Specialists objects to PSC's Requests to the extent they seek the production of electronic documents that would be unduly burdensome or costly to search for, collect and produce.
13. Pain Medicine Specialists reserves the right to supplement and/or amend these objections pursuant to Federal Rule of Civil Procedure 26(e).
14. Pain Medicine Specialists incorporate by reference, the other general objections raised by other medical providers to the identical subpoenas served upon them and filed with this Court.

SPECIFIC OBJECTIONS

Pain Medicine Specialists objects to the Subpoena issued by the PCS on the following grounds:

- The Subpoena exceeds the limited scope of discovery allowed by the MDL Court.
- Pain Medicine Specialists has no plaintiffs in this litigation.
- The Subpoena violates Maryland law and HIPAA and has failed to provide proper notice to the patients before seeking the information.
- The Subpoena violates Fed. R. Civ. P. 26(b) in that it is unduly burdensome and seeks information that is wholly irrelevant to the MDL.
- The Subpoena seeks information outside of the control of Pain Medicine Specialists.
- The Subpoena violates Fed. R. Civ. P. 45(c)(3)(A)(iii) in that it seeks privileged information.

I. PSC's Subpoena Goes Beyond the Authority Granted by the Court to Conduct Discovery.

Pain Medicine Specialists objects to portions of the Subpoena that seek the discovery of documents that are neither relevant to the issues raised in this action nor are reasonably calculated to lead to the discovery of evidence admissible in this action. On June 21, 2013, the MDL Court issued two Orders governing discovery; the "Order Granting Plaintiffs Leave to Serve Subpoenas and Qualified Protective Order Regarding Protection of Health Information" ("QPO") and the "Order on Central Enforcement of Subpoenas" ("Enforcement Order"). These Orders outline the scope of discovery the PSC were permitted to seek through the issuance of non-party Subpoenas. The Subpoena served by the PSC, however, far exceeds this authority.

First, the QPO provided that

[t]he information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications

or compounds from January, 2011 – November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.

(*See* June 21, 2013 Order 112).

PSC's Subpoena, however, has requested categories of documents, including documents far outside the permitted scope of discovery. The Subpoena demands, among other documents:

- Information about NECP including its credentials, accreditations, regulatory compliance. ¶8
- All policies of insurance, including professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies issued to Pain Medicine Specialists. ¶17
- Articles of Incorporation and/or By-Laws applicable to Pain Medicine Specialists. ¶18

None of these documents are remotely within the scope of the Court's Order.

In addition, as the last phrase from the Order made clear, the requested documents must have some relevance to the action the PSC is prosecuting and it cannot simply conduct a fishing expedition. Since Pain Medicine Specialists is not involved in the MDL and has no claimants in the litigation, it is unfamiliar with the scope of the claims made by PSC against NECC and others. At a minimum, prior to this Court permitting the PSC to engage in this broadly worded discovery request, it must demonstrate relevance of each request to the claims involved in these proceedings. The burden of demonstrating such relevance is appropriately placed on the PSC since it seeks to go beyond the Court's Order and it has served the subpoena on Pain Medicine

Specialist which is an innocent third party to this litigation. Before Pain Medicine Specialists undertakes the expense and burdens demanded in the Subpoena, the PSC must be compelled to explain how each request is relevant to the claims. It has failed to do so.

The PSC's Subpoena requests documents and information that are far outside the scope of permitted discovery. The overreaching of the Subpoena shows PSC's intent to conduct a fishing expedition for potential clients and/or an effort to intimidate and harass healthcare providers who PSC would like to be potential defendants. The Subpoena must be quashed.

II. None of Pain Medicine Specialists' Patients are Plaintiffs in this Litigation.

Pain Medicine Specialists understands that PSC no longer seek documents or information concerning the identification of Pain Medicine Specialists' patients who received NECC medications, other than those from the tainted lots. Accordingly, Pain Medicine Specialists will not produce information in response to those requests. To the extent Plaintiffs seek information concerning patient identification outside the scope of the information required under the Bankruptcy Bench Order, Pain Medicine Specialists objects on the grounds that such information is neither relevant to the issues raised in this action nor reasonably calculated to lead to the discovery of evidence admissible in this action. The Bankruptcy Court properly determined that patients who did not receive tainted NECC medications were not personal injury "victims" entitled to notice of the upcoming Bar Date.

Pain Medicine Specialists objects to the portions of the Subpoena that seek the discovery of non-patient identifying information or documents that are beyond the reduced scope of the Bankruptcy Court's order. Pain Medicine Specialists respectfully requests that the Court determine that, with the limited disclosure of information requested by the Bankruptcy Court, Pain Medicine Specialists has fully met its reasonable obligations under the Subpoena.

Despite the PSC promising to identify claimants, Plaintiffs have failed to identify a single Pain Medicine Specialists' patient who has filed a claim or joined the MDL. As far as Pain Medicine Specialists is aware, none of its patients have contracted fungal meningitis or suffered from other injuries in connection with the tainted NECC medications. Consequently, none of the documents that the Plaintiffs seek are relevant to the claims of any parties in the MDL and Plaintiffs' broad requests are not reasonably calculated to lead to the discovery of such evidence.

Moreover, several of Plaintiffs' requests seek documents that do not involve NECC or the fungal meningitis outbreak at all. For example, they seek Pain Medicine Specialists' articles of incorporation and by-laws for the years 2011, 2012, and 2013. Request Nos. 18 & 21. Pain Medicine Specialists' organizational structure, leadership structure, and governance documents are not relevant to any of the claims at issue in the MDL. Requests such as these thus do not comply with FRCP 26(b)(1). Accordingly, Pain Medicine Specialists requests that this Court modify the Subpoena so as to limit Plaintiffs' requests to documents relating to Pain Medicine Specialists patients who received medications from the NECC tainted lots.

III. The Subpoena Has Failed To Provide Protection And Notice To Patients Necessary To Ensure Their Privacy Rights.

Pain Medicine Specialists further objects to the requests in the Subpoena to the extent that they call for information protected from disclosure by the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d et seq. (HIPAA) and regulations promulgated thereunder, under the Health Information Technology for Economic and Clinical Health (HITECH) Act, 42 U.S.C. 1176a et seq. and regulations promulgated thereunder, and more importantly, under Maryland's Medical Records Privacy Act, Md. Health-General Code Ann. § 4-301, et seq. Maryland's Act was enacted to ensure that the privacy of patients is protected and that they begin adequate notice and an opportunity to protect the release of any medical records

relating to them. Md. Health-General Code Ann. § 4-305. The PSC has not shown that it has provided any notice to the patients whose records may be sought under the Subpoena. Without this minimum protection guaranteed to Maryland residents (and concomitant penalties on the medical providers releasing those records without proper authorization), any medical records cannot be produced under the Subpoena.

The PSC's Subpoena also obviously calls for information that is Protected Health Information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. § 164.501 *et seq.* As a "covered entity" under HIPAA, Pain Medicine Specialists has a duty to keep patients' Protected Health Information confidential. Disclosure to third-parties may only be made under limited circumstances. Though this Court's QPO provided that "[t]he information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions..." (Dkt. No. 192), the Subpoena requests a range of patient Protected Health Information far outside that narrow scope.

Though the Court's Order Granting Leave purported to establish a procedure for production of HIPAA-protected information to create a "safe harbor," the PSC's Subpoena so far exceeds the scope of discovery authorized by the Court that the "safe harbor" is likely to be ineffective. Non-party Pain Medicine Specialists should not be required to violate, or risk violating, HIPAA and state privacy and confidentiality laws, especially in light of the lack of relevance and duplicative nature of the information demanded by the Subpoena.

In addition, the Bankruptcy Bench Order covers only protected health information for patients who received tainted NECC medications. Yet, several of the Subpoena's requests would require Pain Medicine Specialists to produce information and documents relating to patients who received or for whom medications were ordered from the non-tainted NECC lots or did not

receive NECC medications at all. If Pain Medicine Specialists produced such information, it would be outside the protection of the Bankruptcy Bench Order and would violate its patients' Privacy Rights under HIPAA and HITECH.

Pain Medicine Specialists requests that the Court modify the Subpoena to require Pain Medicine Specialists only to produce information protected Bankruptcy Court Bench Order, specifically to provide the names and other information for patients who Pain Medicine Specialists can confirm received tainted NECC medications.

IV. PSC's Subpoena is Unduly Burdensome for Pain Medicine Specialists.

Given that Pain Medicine Specialists is a non-party to the MDL action, compliance with the overly broad Subpoena would require a tremendous amount of time, money and other resources. A Court is required to quash a Subpoena if it "subjects a person to undue burden." Fed.R.Civ.P. 45(c)(3)(A) (*see also S.E.C. v. White*, 2011 WL 1544202 (D.S.C. 2011)). Whether a Subpoena is unduly burdensome within the meaning of Fed. R. Civ. P. 45(c)(3)(A)(iv) raises the question of the reasonableness of the Subpoena, which requires that the court "[weigh] a Subpoena's benefits and burdens and consider whether the information is necessary and whether it is available from any other source." *Maxtena, Inc. v. Marks*, 289 F.R.D. 427 (D. Md. 2012). The information and documents demanded by the PSC's Subpoena is so overly broad that this balance weighs in favor of the Subpoena being quashed. The majority of the information sought by the Subpoena is not relevant and is not reasonably calculated to lead to the discovery of relevant evidence. Fed. R. Civ. P. 26.

For example, Pain Medicine Specialists' corporate documents and insurance policies have no relevancy to the allegations being litigated through the MDL, nor does the request for vast amounts of information about Pain Medicine Specialists' relationships with other

compounding pharmacies. Further, any information that may be relevant is readily available from other sources, such as the FDA, CDC or Maryland Department of Health. The PSC has not made any effort to show that the information cannot be obtained from other sources or that it has not been able to obtain this information elsewhere.

Despite having guidance from the MDL Court as to what topics and date ranges were permissible targets for discovery, the PSC has blatantly disregarded that guidance and embarked upon an attempt to obtain a massive amount of private, privileged and irrelevant information. The PSC's Subpoena is an obvious fishing expedition meant to reach additional clients. Given the overbreadth of the Subpoena and the substantial cost in time and money that compliance would cost, not only is the Subpoena unduly burdensome, but the PSC failed its duty to take reasonable steps to avoid imposing undue burden upon Pain Medicine Specialists, in violation of Fed. R. Civ. P 45(c)(1).

Pain Medicine Specialists objects to the Subpoena to the extent it purports to impose burdens other than or beyond those imposed by the Federal Rules of Civil Procedure ("FRCP"), the Local Civil Rules of the United States District Court of Massachusetts or Maryland, or any current or future orders of this Court. As noted above, none of Pain Medicine Specialists' patients are parties to any of the litigations that comprise the MDL and none have filed suit against Pain Medicine Specialists in any forum in relation to NECC medications. Therefore, Pain Medicine Specialists does not have any documents relevant to resolving any of the claims at issue in the MDL. Rather than tailor their requests to avoid placing an undue burden on Pain Medicine Specialists, Plaintiffs demand broad categories of documents that would be burdensome and expensive for Pain Medicine Specialists to locate and produce.

For example, the Subpoena calls for documents and information about Pain Medicine

Specialists' relationships with other pharmacies and drug manufacturers. Those vendors are not parties to the MDL actions nor have they been linked to the fungal meningitis outbreak in any way. Accordingly, these requests and others like them are overly broad and unduly burdensome and do not comport with FRCP 45(c)(1). Pain Medicine Specialists requests that the Court modify the Subpoena to limit Plaintiffs' requests to documents and information that are relevant to the claims at issue in the MDL, namely documents and information relating to medications administered to patients from the tainted NECC lots. In addition, Pain Medicine Specialists requests that the Court order Plaintiffs to reimburse Pain Medicine Specialists under FRCP 45(c)(1) for costs and fees it incurs in connection with all proceedings related to the Subpoena.

V. The Subpoena Seeks Information Outside of Control of Pain Medicine Specialists.

Pain Medicine Specialists objects to the Subpoena to the extent it calls for production of documents outside of Pain Medicine Specialists' possession, custody, control, in Plaintiffs' possession, custody or control, readily available to Plaintiffs, or attainable by Plaintiffs from public sources, including but not limited to the Food & Drug Administration, Centers for Disease Control, or other federal, state or local government agencies.

For example, the Subpoena seeks documents pertaining to NECC sales materials and sales agents. Plaintiffs can and should obtain any information concerning NECC's sales force or NECC's marketing materials from NECC, which is the central party to this litigation. Such requests are overly broad, unduly burdensome, and in excess of FRCP 45. Pain Medicine Specialists requests that the Court modify the Subpoena so as to limit Plaintiffs' requests to documents solely within Pain Medicine Specialists' exclusive custody and control.

More importantly, Pain Medicine Specialists' is not in a position to provide

information to the PSC which has been received from any state agencies which would necessarily include any grand jury subpoenas. This information is subject to government limitations and restrictions and cannot be broken by simply issuing a subpoena to a third party. To the extent that the PSC desire to obtain any of this information, they must obtain it directly from the government agencies and third parties.

VI. The Subpoena Violates Fed. R. Civ. P. 45(c)(3)(A)(iii) in that it Seeks Privileged and Proprietary Information.

Pain Medicine Specialists objects to the Subpoena to the extent it calls for the disclosure of confidential or proprietary business information. For example, the Subpoena calls for documents relating to Pain Medicine Specialists' compliance policies and procedures and vendor selection processes. These requests would call for Pain Medicine Specialists to produce non-public information relating to its internal business practices. Given that Pain Medicine Specialists is not a party to the MDL and many of the documents Plaintiffs seek are wholly irrelevant, Pain Medicine Specialists should not be forced to disclose this sensitive business information. Pain Medicine Specialists requests that the Court modify the Subpoena so as to limit Plaintiffs' requests to non-confidential documents.

Finally, the Subpoena calls for information that may be protected by the attorney/client or work product privileges. Particularly items 15 and 16 on Exhibit B to the Subpoena call for all communications on the subject of the recall and likely include attorney/client communications.

Objections to the Request for Deposition Testimony

Plaintiffs stated at the July 18 Status Conference that they have indefinitely adjourned their request for deposition testimony by corporate representatives from Pain Medicine Specialists on certain designated subjects. To the extent that the deposition requests have not been adjourned, Pain Medicine Specialists incorporates its above objections into its objections concerning the

request for deposition testimony. Where the Court modifies or limits Plaintiffs' requests for documents, Pain Medicine Specialists requests that it also modify and limit Plaintiffs' corresponding requests for testimony related to those documents.

CONCLUSION

For the above-referenced reasons, Pain Medicine Specialists respectfully files these objections and requests that the Court quash or modify the Subpoena or, in the alternative, issue a protective order under FRCP 26(c).

/S/Donald J. Walsh

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CERTIFICATE OF SERVICE

This will certify that a true and accurate copy of the foregoing was served on all parties hereto by virtue of the Court's electronic filing system this 16th day of August, 2013 and paper copies will be sent to those indicated as non-registered participants.

/S/Donald J. Walsh

Donald J. Walsh